MONTANA STATE HOSPITAL
POLICY AND PROCEDURE

ADVERSE DRUG REACTION REPORTING

Effective Date: August 1, 2012 **Policy #:** PH-10

I. PURPOSE: To establish a mechanism to ensure that adverse drug reactions are systematically reported and reviewed.

II. POLICY: Montana State Hospital direct care staff, in cooperation with the pharmacy, has the responsibility of reporting, documenting, and monitoring adverse drug reactions that occur within the facility's population.

III. DEFINITIONS:

A. Adverse drug reaction (ADR) is any noxious, unintended, undesirable, or unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease, or for modification of psychological function. This definition is understood to exclude predictable, dose-related side effects due to drugs which result in little or no change in patient management, and in particular, mild extrapyramidal side effects due to neuroleptic drug therapy.

B. Indications of an ADR include anaphylaxis, arrhythmia, convulsions, hallucinations, shortness of breath, rashes, itching, hypotension, dystonia, leukopenia, urinary retention, symptoms associated with neuroleptic malignant syndrome, initial report of tardive dyskinesia, EPS related to non-antipsychotic drugs and also includes true allergic (hypersensitivity) reactions and idiosyncratic reactions.

A significant adverse drug reaction is one that:
- requires discontinuing the drug
- requires large, (greater than 50%) dosage decrease
- necessitates admission to an acute care hospital
- delays anticipated discharge/placement from Montana State Hospital
- necessitates supportive treatment
- significantly complicates diagnosis
- negatively affects prognosis
- results in temporary or permanent harm, disability, or death.

IV. RESPONSIBILITIES:

A. Direct Care Staff: Observe and report suspected adverse drug reactions.

B. Licensed Nurses: Observe, report, document and begin ADR report.

C. Psychiatrist/Physician: Observe, assess, prescribe, document and complete ADR report.

D. Pharmacist: Evaluate report, present ADR report to Pharmacy and Therapeutics Committee.

E. Pharmacy and Therapeutics Committee: Evaluate ADR report, make recommendations, and submit to the Quality Improvement Committee.

F. Medical Director: Evaluate and submit significant ADR reports to FDA and manufacturer.

V. PROCEDURE:

A. Reporting:

1. Any staff who witnesses a suspected adverse drug reaction will notify the RN/LPN on duty.
2. The RN/LPN will immediately contact the attending psychiatrist/physician and nursing supervisor to report the possibility of an adverse drug reaction.
3. The RN/LPN will complete the nursing section of the Adverse Drug Reaction Report (Attachment A).
4. The physician will examine the individual, order necessary intervention, if needed, and will complete the medical section of the Adverse Drug Reaction Report.
5. The physician will forward the report to the pharmacy for evaluation by a registered pharmacist and the Pharmacy and Therapeutics Committee.
6. The pharmacist will present the adverse drug reaction to the Pharmacy and Therapeutics Committee for review at the next scheduled meeting.
7. The Pharmacy and Therapeutics Committee will evaluate each report and, when appropriate, will make recommendations for further evaluation by the medical director, to submit significant ADR reports to the FDA, and the manufacturer.
8. The physician may also note the presence of an ADR on the order sheet, prompting the Pharmacy to send an ADR report to the physician.

B. Documentation:

1. The RN/LPN will document in the patient's medical record, all the events associated with reporting the suspected ADR to include, but not limited to:

    a. signs and symptoms which prompted the ADR reporting procedure; and

b. date and time the physician and nurse supervisor were notified of the suspected ADR.

2. The physician will document in the patient's medical record, the adverse drug reaction along with the interventions, if any were necessary.

3. The pharmacy will maintain all ADR reports and communicate pertinent data related to these reports to the Quality Improvement Committee no less than yearly.

VI. REFERENCES: None

VII. COLLABORATED WITH: Pharmacy Director, Director of Nursing Services, Quality Improvement Director, Pharmacy and Therapeutics Committee Chair

VIII. RESCISSIONS: #PH-10, *Adverse Drug Reaction Reporting* dated July 1, 2009; #PH-10, *Adverse Drug Reaction Reporting* dated August 22, 2006; #PH-10, *Adverse Drug Reaction Reporting* dated March 31, 2003; Policy # NS-01, *Adverse Drug Reaction Reporting* dated February 14, 2000; H.O.P.P #NS-02-96-N, *Adverse Drug Reaction Reporting* dated May 31, 1996

IX. DISTRIBUTION: All hospital policy manuals.

X. ANNUAL REVIEW AND AUTHORIZATION: This policy is subject to annual review and authorization for use by either the Administrator or the Medical Director with written documentation of the review (Attachment B) per M.C.A. § 307-106-330.

XI. FOLLOW-UP RESPONSIBILITY: Medical Director

XII. ATTACHMENTS:

A. Adverse Drug Reaction Report Form

_____/___/__	_____/___/__
John W. Glueckert Date	Thomas Gray, MD Date
Hospital Administrator	Medical Director

MONTANA STATE HOSPITAL
ADVERSE DRUG REACTION REPORT

PART I (To be completed by RN/LPN)

Patient's Name: _____ MSH #_____ Unit: _____

Date of ADR: _____

Description of Reaction: (Also document in Progress Notes)

Current & Recent Medications (include dose & frequency)

1.	6.
2.	7.
3.	8.
4.	9.
5.	10.

_____
Signature of RN/LPN Date

PART II (To be completed by physician)

Summary of Clinical conclusions (Include relevant medical and lab data)

Specify implicated suspected drug: _____

Recommendations/Actions taken (also document response in Progress Notes)

_____
Signature of Physician Date

PART III (To be completed by Pharmacy and Pharmacy & Therapeutics Committee)

ASSESSMENT OF ADR

1. TYPE (check one)

A. _____ Type A reactions are the result of an exaggerated, but otherwise normal, pharmacological action of a drug given in the usual therapeutic doses.

B. _____ Type B reactions are totally aberrant effects that are not to be expected from the known pharmacological actions of a drug when given in the usual therapeutic doses to a patient whose body handles the drug in the normal way.

Reaction was responded to appropriately? [ ] YES [ ] NO

Pharmacy & Therapeutics Review & Recommendations:

Refer to Medical Director	[ ] YES	[ ] NO
Report to FDA	[ ] YES	[ ] NO
Report to Manufacturer	[ ] YES	[ ] NO

_____

Signature of P & T Committee Chair Date